Regulatory change in pharmaceutical prices: Evidence from a health care reform in Denmark

This version: Nov. 30, 2009 [uka] [¶]

Ulrich Kaiser[*], Susan J. Mendez[**], and Thomas Rønde[‖]

Abstract

We study the effect of regulatory change on pharmaceutical prices in the context of a natural experiment in Denmark that started in April 2005 when the Danish government decided to make the extent of a patient's co–payment for pharmaceutical products dependent on the price of the cheapest domestic substitute instead of the European average price. We estimate nested logit models of the demand for lipid modifying agents, products that decrease levels of cholesterol, and combine these estimates with the product–specific price effects of the change in reimbursement rules. We find an increase in the demand and a significant price decrease in wholesale prices, reference prices and co-payment prices. This effect is stronger for products belonging to the most expensive segment. Patients and the Danish health insurance system benefitted from the reform, their total savings in expenditures per period are 2% and 4% respectively. Producers lost on average 3.6% of their revenue per period.

JEL-classification: I18, C23

Keywords: pharmaceutical markets, regulation, co–payment

[¶]We thank Margaret Kyle, Hannes Ullrich, Minjae Song, the participants of the 10th Symposium of the German Economic Association of Business Administration in Vallendar and the participants of the 39th Economic Seminar Ottobeuren — most importantly Felix Höffler and Werner Güth — for helpful comments. We are very much indebted to Jørgen Clausen of the Danish Association of the Pharmaceutical Industry (Lægemiddel Industri Foreningen, lif) for data provision and data advice. Excellent medical advice was provided to us by the MDs Marit Otto, Roland Knudsen and in particular Johannes Schmid.

[*]University of Zurich, Institute for Strategy and Business Economics, Plattenstr. 14, 8032 Zurich, Switzerland, ulrich.kaiser@isu.uzh.ch; Centre for Economic and Business Research at Copenhagen Business School, Centre for European Economic Research and Centre for Industrial Economics at the University of Copenhagen.

[**]University of Zurich, Institute for Strategy and Business Economics, Plattenstr. 14, 8032 Zurich, Switzerland, susan.mendez@isu.uzh.ch;

[‖]Copenhagen Business School, Department of Innovation and Organizational Economics, Kilevej 14A, 2000 Frederiksberg, Denmark, thr.ino@cbs.dk; Centre for Economic and Business Research at Copenhagen Business School; Centre for European Economic Research; Centre for Industrial Economics at the University of Copenhagen and Centre for Economic Policy Research.

1 Introduction

Given the steadily growing live expectancy and the expected launch of new and ever more expensive pharmaceutical products, it is to be expected that expenditures for pharmaceutical products will increase substantially over the next few years. This leads and has led governments around the world to regulate the market for pharmaceuticals.

A major regulatory instrument are cost containment tools. These include price caps, price agreements with companies, substitutions schemes, monitoring of prescription behavior and reference price indices. Denmark introduced reference pricing in 1993 and changed the way reference prices were calculated on April 1, 2005. The latter is the regulatory change this paper investigates. Prior to that date, reference prices were calculated according to an average of European prices. Denmark now operates under a reference pricing scheme where reimbursement rates depend on the price of the cheapest substitute product available in Denmark, which is defined as the "reference" product. Moreover, pharmacies must dispense the reference product. Patients may choose to buy the reference product or a more expensive product but must pay the difference between the chosen medicine and the reference product out of their own pockets.

This article aims at investigating the effects of this policy change on both consumer expenses and insurance expenses. We focus our analysis on statins. These belong to the group of lipid modifying agents (LMAs), which are used to treat abnormally high levels of cholesterol[1]. LMAs are also prescribed in the aftermath of diseases related to the coronary system after a large–scale medical trial in Scandinavia in the 1990s has been able to show that treatment with Simvastatin, an important LMA, has a lowering effect on mortality and morbidity (Scandinavian Simvastatin Survival Study Group, 1994). Statins are widely prescribed drugs and have experienced rapidly increasing demand in the past years all over the world. They presently constitute the best selling drug in terms of sales in Denmark. The most prominent examples of statins sell under the names "Zocor" and "Lipitor".

Our empirical strategy is first to estimate a structural model for the demand for LMAs for the period before the regulatory change was announced, using a nested logit model of product differentiation (Anderson et al. 1992; Berry 1994), a discrete choice model with random consumer utility. We hence focus on the "treatment on the treated", in other words, the effect of the health care reform on products that already existed before the change. We assume that price elasticities are time invariant and make predictions about the change in demand associated with the regulatory change. We then estimate the *product–specific* effect of regulatory change on prices

[1]Table (8) in the Appendix gives an overview of the classification of lipid modifying agents

using the Pooled Mean Group Estimator due to Pesaran and Smith (1995). Finally, we link the own–price elasticities of demand calculated from our demand model with our estimated price effects to calculate changes in consumers co–payments and insurance expenditures.

In contrast to the existing studies we are aware of, we explicitly differentiate between list prices and co–payment prices. The latter are prices patients actually pay. We believe this distinction is important since patients will be much less price sensitive if reimbursement rates are high than if they are low. Furthermore, we consider the joint effects of reimbursement reform on prices and quantities. More importantly, we are able to calculate the effect of regulatory change on both consumers and health insurances, an issue that is truly novel to the literature as far as we know.

Our paper is neither the first to empirically look at the price effects of regulatory change in pharmaceutical markets nor the first to analyze the joint effect of regulatory change on prices and demand. Pavcnik (2002) provides insights on whether an increase in patients' co–payments affects the pricing behavior of producers. She exploits the introduction of reference pricing in Germany in 1989 and finds that prices decreased significantly. The focus lies in the different reaction of branded and generic producers. In her theoretical study, Miraldo (2009) develops a model to analyze the effects of reference pricing policy on firms pricing strategies. First, she focuses on two scenarios where the reference price is calculated in alternative ways and then she allows for quality differences among products. Her results suggest that if the reference price is the minimum of all observed prices, firms cannot coordinate on higher prices, while firms are able to coordinate when the reference price is calculated as a linear combination of firms' prices. If these predictions are correct, we should find a decrease in prices in our data as well.

A series of studies of a regulatory change similar to the Danish one has been published for Norway. Norway switched from price cap regulation to reference pricing in 2003 for a sample of off–patent products. Brekke et al. (2008) find strong evidence for the policy reform's negative effect on price levels. Dalen et al. (2006) is the first study we are aware of, that simultaneously investigates price and demand effects of a regulatory reform. They also estimate a logit–type model to evaluate market power before and after the reform. They assume that there is not consumer purchase decisions that are not directly related to prices or qualities of the observed pharmaceutical products. The absence of an "outside good" implies that total demand for pharmaceutical products is inelastic, an assumption that does not square well with rapidly increasing overall demand, at least for statins. By contrast, our study explicitly allows for the existence of an outside good which, in the case of LMAs include a healthier

diet and more exercising.

A common feature shared by almost all studies on pharmaceutical markets is the use of therapeutic groups as the comparison unit. That is, products that are used for the treatment of the same disease are considered "substitutes", even if they do not share the same active substance and in fact may be complements like blood thinners and LMAs in the case of coronary diseases. Our study assumes that all products within the group of statins are potential substitutes and that their degree of substitutability depends on the respective types of active substances and dosages. We believe our definition of substitutes is more appropriate since a patient's purchase decision is limited by the practitioner's prescription, where the active ingredient and its dosage are explicitly described.

This paper is organized as follows: Section 2 gives an overview of the market for pharmaceutical products followed by a review of the Danish institutional settings. Section 3 describes the data and Section 4 describes the empirical strategy. Section 5 shows the results of the empirical analysis and Section 6 the policy implications. Section 7 concludes.

2 The Danish market for pharmaceutical products

2.1 General settings

The pharmaceutical industry has been the subject of an extensive number of studies on market dynamics, price dispersion and policy evaluation. Danzon (2000) gives an excellent survey of the international literature.

As in other European countries, the market for pharmaceutical products in Denmark is regulated. Denmark follows European regulations regarding product authorization. Product pricing and reimbursement rules are national matters, as well as pharmacies. The number of pharmacies, their location and total gross profit is determined by the Danish Ministry of Health and Prevention. Prices for prescription-only products are identical nationwide. However, pharmacies can compete on sales prices for over-the-counter (OTC) medicines since these can be sold by non-pharmacies.

The pricing of pharmaceutical products in Denmark is free in the sense that producers are not tied to any regulation regarding price setting. However, they are required to notify their pharmacy purchase price (PPP) to the Danish Medicines Agency (DKMA) every 14 days.

In Denmark, every resident is entitled to free and equal access to tax–supported health care services regardless of her employment status. In the provision of pharmaceutical products, the government reimburses prescription drugs based on the patient's

prior annual drug consumption within a reimbursement period, measured in terms of reference prices.

Even though the popularity of additional private insurances has been increasing lately, it was not very common during the period we observed. In 2000 over 70% of the population was covered only by the statutory health insurance. The dominant firm in private insurance, practically a monopolist, is "Sygeforsikringen Danmark". The by far most popular insurance plan pays 50 percent of the patient's co–payment and covers 80 percent of all subscribers. We do not have information on private insurance membership which means that we cannot deal with possible selection problems arising from additional private coverage. Because the fraction of private insurance providers is small and it is not clear if healthier people subscribe more than diseased patients (since diseased applicants would not be admitted) or viceversa (diseased people apply to have a larger fraction of expenses covered), we speculate that the problem of the existence of private insurance is not an important one.

2.2 List prices and co–payments

Our data set contains biweekly prices and sales on LMAs for the period September 15, 2003 to October 9, 2006. Our price data, including reference prices, can be downloaded from www.medicinpriser.dk.

In order to calculate patients' co–payments for the base period, we use the reference prices and define co–payment for patients suffering from high levels of cholesterol as follows:

$$p^c = p^l - (0.8\ p^r),$$

where p^c denotes patient co–payment, p^l is the list wholesale price and p^r denotes the reference price. Hence, the minimum co–payment for each patient (when list prices and reference prices coincide) is 20 percent of the list price. The co–payment fraction is unaffected by the health care reform.

Patients' co–payment is much lower in the UK, Spain and France, where it is only between six and eight percent of total cost, while the Danish co–payment size is similar to that of Sweden (Dalen et al., 2006).

2.3 The April 2005 health care reform

The health care reform that this paper looks at, is the change in the way reimbursement rates are calculated. Denmark kept its reimbursement system based on reference prices but the way the reference price was calculated changed in April 2005.

$$
\begin{aligned}
p^r_{before} &= \begin{cases} p^{EU}, & p^l \geq p^{EU} \\ p^l, & p^l < p^{EU} \end{cases} \\
p^r_{after} &= min(p^l, \quad p^l \in P)
\end{aligned}
$$

Before April 1, 2005, the reference price (p^r) was set equal to the average price among members of the European Union in 2001 (p^{EU}), excluding Greece, Luxembourg, Spain and Portugal. If no European price existed or if the Danish price was lower than the average European price, then the reference price was set equal to the listed price of the product. For parallel imports the reference price was defined as the price of the directly traded pharmaceutical. According to a report from the Danish Ministry of Health from 2004, 74 percent of the packages sold on the Danish market were cheaper than the corresponding European price. After April 2005, the reference price was set to be the lowest price within the group of substitutable products in Denmark and is updated every second week.

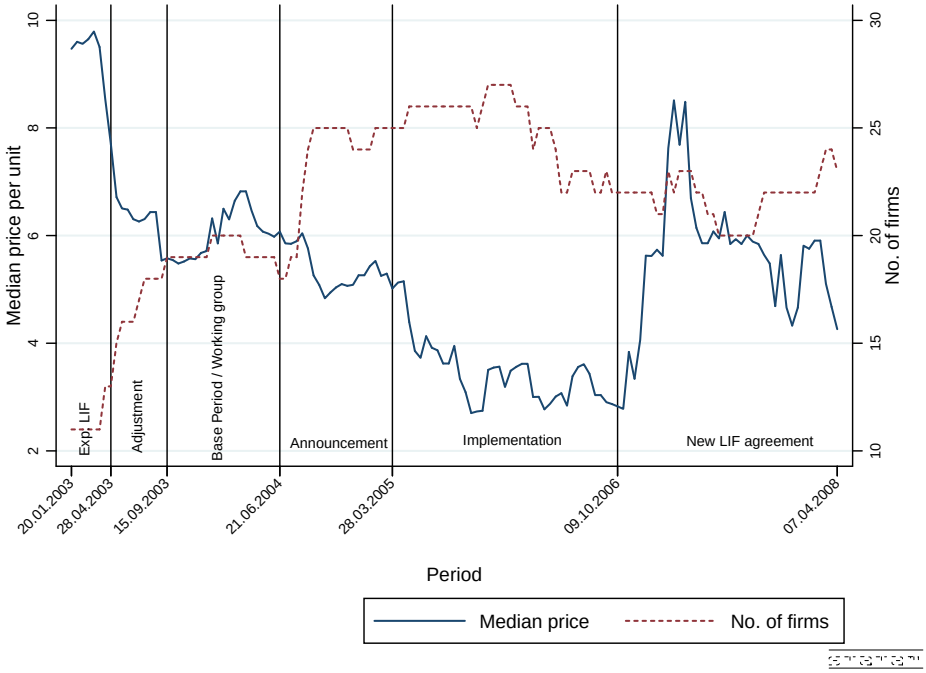
In order to favor generic substitution, the so–called "G Scheme" was introduced in 2001. This scheme states that pharmacists are obligated to hand out the cheapest product within a group of substitutes unless the prescription explicitly requires no substitution, which is the case for just five percent of all prescriptions, or the patient explicitly requests another product. If the patient request a more expensive product, she must pay the difference out of her own pockets. Table (1) gives an example. Suppose a patient can choose among three products. After the reform the reference price is equal to price of the cheapest product in Denmark ($p^r_{After} = p^l_A = 100$ DKK), the patient obtains maximal reimbursement when buying the cheapest product paying only 20 DKK. However if the requested product is C, the patient receives a reimbursement of 80 DKK (0.8 p^r) and have to pay 120 DKK by herself.

Table 1: calculation of co-payment

Product	p^l	p^{EU}	p^r_{before}	p^r_{after}	p^c_{before}	p^c_{after}
A	100	150	100	100	20	20
B	150	150	150	100	30	70
C	200	150	120	100	80	120

2.4 Treatment and control periods

Our empirical analysis is practically an event study: we investigate changes in pharmaceutical pricing before and after the change in the reimbursement system. There are two relevant dates that were set by the Danish government. In October 2004 the



Danish parliament ratified the new reimbursement law and In April 1, 2005 the law was implemented. Both dates are considered in the empirical analysis.

It seems likely, however, that information regarding the changes in reimbursement rules has been at the disposal of market participants prior to these legislature–determined dates. To further investigate this issue, we consulted newspaper and trade press archives searching for the appropriate keywords. It turned out that the Danish Minister of Health (who became Prime Minister in 2009) announced on September 17, 2003 to assemble a group of experts with the aim at changing the existing reimbursement system to strengthen competition. Moreover, as a member of the working group, the Danish Association of the Pharmaceutical Industry (LIF) launched the idea of calculating reference prices as the minimum of domestic prices on January 3, 2004. These additional events are summarized in Table 2 and complement the announcement and implementation dates considered initially. The period where the Danish Minister of Health initiated the working group serves as our "base period" in the empirical analysis.

We map these event dates to the median price per pill per 14 days in Figure 2.4. This figure represents the complete LMAs market including 341 products during January 20, 2003 to April 7, 2008 for a total of 137 time points. The figure appears to suggest that median prices did indeed change either at one of the specific dates or shortly before/after, an observation that is also shared by simple linear fixed effects regressions on time dummy variables. We therefore define our relevant event dates as

discussed in this subsection.

3 Data

3.1 Definitions

Product definition

Each pharmaceutical product is characterized by its name, package size, form, strength, anatomical therapeutic chemical classification code (ATC) and producer name. A product may for example be defined as "Zocor" with 98 tablets à 20 milligram of the active substance simvastatin, ATC: C10AA01, produced by the firm Merk Sharp & Dohme.

The ATC-code is a combination of five letters and numbers that precisely describes a product's active substance. We focus our analysis on the market for statins (254 products) during the dates defining base, announcement and implementation period (September 15, 2003 to October 9, 2006) for a total of 80 time observations. Statins are placed in eight different ATC classes of which six are marketed in Denmark[2]. The statins in our sample are all either pills, coated pills or capsules with the smallest package size being 28 pills and the largest one being 250 pills. The strength of the products, defined as the amount of active substances per pill, also varies considerably, namely from four milligrams to 600 milligrams per pill.

Measurement units

We convert all prices and quantities, originally measured in per–package units, into prices and quantities per pill in order to make prices and quantities comparable across different package sizes.

Prescription

We spoke to medical practitioners from internal medicine, neurology and to a general practitioner about their prescription behavior. When treating a patient, they follow the recommendations issued by the "Institute of Rational Pharmacotherapy" (IRF) and simultaneously make a choice of active ingredient and dosage. IRF recommends to start with statins and prescribe other LMAs only under certain circumstances, for example intolerance to statins or if the patient shows high levels of triglycerides.

Substitutes

Pharmacist can only substitute among products with the same active substance, same strength and same package size indicated in the prescription. We hence define substitution groups with these characteristics.

Branded products

[2]see Table (8) for the classification of LMAs and Table (9) for the market shares of statins.

Another dimension of differentiation in pharmaceutical products is whether or not a product is "branded", i.e. whether it possesses a protected name as the original product. Each ATC group has at least one product that is a branded drug. For example, "Zocor" produced by Merck Sharp & Dohme is the branded name for the active substance "Simvastatin". In our sample a total of 50 products are branded, corresponding to almost 20 percent of all products. Of the total of 30 producers only six supply branded drugs.

3.2 Source

Prices, reimbursement status and other product characteristics are published on URL "www.medicinpriser.dk". The website, maintained by DKMA , has been available since 1998. It contains, however, data only for five consecutive years at any point in time.

The site publishes a list of all authorized pharmaceutical products marketed in Denmark. Since February 2003, prices are updated every second Monday based on changes notified by companies during that period. The data is publicly available and was created to help citizens calculate their reimbursement rate and inform them about alternative substitution options. www.medicinpriser.dk is also used by general practitioners when issuing prescriptions, by hospitals for their electronic patient records and by pharmacies in order to ensure uniform prices for prescription drugs at a national level.

We merged the collected biweekly pharmacy retail prices with information on sales volumes. Our sales volume data is proprietary and was made available by the Danish Association of the Pharmaceutical Industry. It comes with the same periodicity as the price data. Table 3 present a descriptive overview of prices and the competitive situation for the three considered block periods. Prices are in 2005 Danish Crowns.

List prices per pill decreased on average 20% from the base period to the implementation period. Reference prices show a decrease of 28% on average, while co-payment prices decreased only 0.4% on average after implementation. On the other hand, sales, measured in number of pills sold every 14 days, increased around 20% on average.

The average number of products in each period varies between 143 and 150, while the average number of firms in each period increased over time from 19 to 25. Producers that belong to the same company form a conglomerate, on average there are 15 to 17 conglomerates in each point of time.

The table confirms what it is mapped in the figure, an increase in the average number of products entering, specially from the base period to the announcement period. The number of products exiting at each point of time increases lightly.

While the share of branded products steadily decreases over all periods, the two measures of concentration, the Herfindahl Index and the three-firm concentration ratio, increased over time, reaching on average 28% and 72% respectively.

4 Empirical strategy

4.1 Elements

Our empirical analysis proceeds in three steps. We first estimate the effects of the change in the reimbursement system of prices for each product, thereby allowing for full heterogeneity in the parameter estimates. Second, we estimate a model of demand for differentiated products. From that model we calculate the own–price elasticity of demand. We use observations from the "base" period only and make the perhaps very reasonable assumption that the reform changed prices but not price elasticities. Third, we calculate the effects of the change in the reimbursement system on demand by linking the estimated own–price elasticity of demand and the estimated effects of the reform on product prices.

It is important to note that our analysis only makes predictions for the products that already existed in the "base" period.

4.2 Price evolution

Before estimating the effects of the reform on prices, we calculate the changes in prices non-parametrically under two scenarios. Scenario 1 keeps demand and list prices constant allowing only reference prices to react to the reform. Scenario 2 allows both reference prices and list prices to change but keeps demand constant. Additionally, we summarize the results for different segments of products, classified according to its distribution of prices in the base period, this results in 4 groups, the first (0%-25%) group represents the cheapest products in the base period, while the last group (75%-100%) represents the most expensive group of products. Table 4 summarizes the results for the comparison base period to implementation period.

For the first scenario, reference prices increased on average 2.5% for all products. While reference prices increased on average 33.7% for the most expensive products, it decreased on average 0.6% for the cheapest group. Co-payment prices change positively and showed the highest increase for the products that were more expensive in the base period. The government saved on average 2% each period and the patients payed around 6% more per period.

In the second case reference prices and list prices decreased on average for all groups. Co-payment prices increased for the most expensive and for the cheapest

products, but showed a negative change for the groups in between. Government and patients saved around 8% and 10% respectively. Producers, on the other hand, lost around 10% of revenues.

Figure 2.4 showed that the different steps in the health care reform have been associated with changes in prices as far as median prices are concerned. However, these median effects may be the outcome of very heterogeneous product–specific effects. We therefore estimate the effects of the different steps in the health care reform product–by–product, thereby allowing for maximal heterogeneity in the effects of the reform on product prices.

The decisive price from a consumer's perspective – the actor that reaches the eventual purchase decision – is the co–payment, p^c, which is the price we link to the different reform steps. We estimate the *average* changes in prices across time by mapping the natural logarithm of co–payments to dummy variables for each block period:

$$ln(p^c_{jt}) = \gamma_{jt} + \theta^A_{jt} T_A + \theta^I_{jt} T_I + \epsilon_{jt}, \tag{1}$$

where T_A denotes a dummy for the announcement period and T_I a dummy for the implementation period. ϵ_{jt} is an iid error term. Note that the parameter estimates are specific to each product j and that identification stems from the long time series dimension of the data. We estimate the parameters separately for each product. While we shall use the individual parameter estimates in our examination of the health care reform, we also present the "Mean Group Estimates" that correspond to Equation (1). These are the means of the coefficient estimates and the procedure we used to generate them is the "Mean Group Estimation" suggested by Pesaran and Smith (1995) in the context of heterogeneous panel data (of which our data is an example).

Estimation of Equation (1) is, as in the demand analysis, restricted to products that already existed in the base period since these are the only ones that were fully affected by the health care reform.

The time dimension of our data in principle allows us to estimate much more flexible functional forms of the price equation. We opt for the simple form as in Equation (1) since we would need to aggregate the more flexible results later anyway in order to make period–specific statements. For example, if we included polynomials of time trends, we would have obtained period–specific and product–specific estimates that would be impossible to interpret.

4.3 Demand Estimation

Basic setup

We derive the own–price elasticity of demand for product j based on a nested logit

model (Berry, 1994). The model assumes that the patient/physician alliance chooses to buy the product that provides them with highest utility. Utility depends upon observed characteristics, including price. In contrast to the "simple" logit model of demand which does not allow for systematic differences between products in different groups (e.g. like substitution groups). The nested logit model allows consumer utility to be depend on the membership in groups and subgroups. This allows for much more flexible substitution patterns compared to the "simple" logit model where products with the same market shares have the same price elasticities.

The idiosyncratic component of consumers' utility is assumed to be iid Gumbel distributed, an assumption that leads to a closed–form solution for market demand and price elasticities.

Consistent with the conversations we had with medical practitioners, we model the choice structure as follows: first, patients and doctors decide whether or not medical treatment is necessary given that the patient has a too high cholesterol level. If treatment is needed, the medical practitioner writes a recipe that specifies the active substance, the strength and package size. The choice of package size is not relevant in our demand estimation since we consider the number of pills, not the number of packages being sold. Second, consumers decide whether or not to buy the cheapest product or a more expensive one. Consumers may want to buy a branded product precisely because of the brand value they attach exceeds the price difference to the generic product. Figure (C) in the appendix shows graphically the decision process.

This leads to the following functional form of our nested logit model:

$$ln(s_{jt}/s_{0t}) = \boldsymbol{x_{jt}}\boldsymbol{\beta} - \alpha p^c_{jt} + \sigma ln(s_{j|gt}) + \zeta_{jt} \quad , \tag{2}$$

where s_{jt} denotes the market share of product j relative to total market size and s_{0t}, denotes the market share of the "outside good" relative to total market size. We shall discuss the definition of these two terms below.

Product–specific characteristics are summarized in vector $\boldsymbol{x_{jt}}$, p^c_{jt} denotes the co–payment the patient needs to make, $ln(s_{j|gt})$ denotes the natural logarithm of product j's market share within group g.

We include package size dummies as our only observed product characteristic since all other observed product characteristics are already included through the definition of groups.

The term ζ_{jt} denotes characteristics of product j that are unobserved to the econometrician.

The nested logit model is consistent with random–utility maximization for $0 \leq \sigma < 1$. Individual i's preferences are uncorrelated across all segments if $\sigma = 0$, then the model collapses into the simple logit demand model.

The outside good

Just like for the well–known individual–level multinomial logit or nested logit model, logit–type demand models for aggregated data require the definition of an "outside good". The outside good is a composite good, it consists of products that are purchased by the consumers instead of the "inside products", in our case statins. In the present case, these would include for example the purchase of homeopathic products, a bicycle or a pair of running shoes. The mean utility of the outside good is normalized to zero and its price is not set in response to the price of the inside goods.

Formally, the market share of the outside good is defined as $s_{0t} = (M_t - \sum_{j=1}^{N} q_{jt})/M_t$, where M_t denote total market size and q_{jt} denotes the quantity of product j being sold at time t. The critical definition of the market size of the outside good hence in the definition of total market size.

We define total market size in terms of the number of pills that would be sold were all potential patients on medication. We downloaded information on the number of patients in any given year that are treated with statins. We then calculate how many pills a median patient takes per 14 days and found that the median patient takes 14 pill per 14 days. That number varies between 11.8 pills in 2002 and 13.6 pills in 2008.[3]

We link this number to potential market size which is based on the conjecture that 80 percent of all Danish residents above the age of 50 have an abnormally high level of cholesterol. We downloaded information on the number of Danish residents above 50 years from Statistics Denmark and calculated the potential number of patients. We multiply that number by the median number of pill a typical patients takes per 14 days and thereby obtain the market size of the outside good. Our estimation results remain unaffected when we change the fraction of Danish residents with an abnormally high level of cholesterol or if we use the maximum or minimum number of pills per 14 days instead of the median number of pills.

Alternative estimators

Nested logit models of demand have been criticized ever since Berry et al. (1995) introduced the "random coefficients" model which is also based on the assumption of iid Gumbel idiosyncratic utility components but which generates much more flexible patterns of substitution. A practical difficulty with the random coefficients model is, however, that its estimation requires price (or other characteristics) data to vary across different markets. This is theoretically discussed in Nevo (2000) and empirically shown by Kaiser and Song (2009). Our price and characteristics data do neither vary across sub-markets as prices and co–payments are uniform across Denmark which is why we resort to our nested logit model. The results form an additional estimation

[3]Note that most pills can be divided into two pieces.

with three nested logit model are presented in the appendix.

4.4 Identification

The unobserved characteristics of product j, ζ_{jt}, are known to both producers and consumers which implies that prices are endogenous in equilibrium and that they have to be instrumented. Not instrumenting prices will lead to downward biased estimates of the price coefficient α. By the same token, the market shares have to be instrumented as well.

The obvious alternative to IV estimation is to control for the unobserved quality characteristics. In principle, this is possible in our setting since the characteristics of pharmaceutical products are time–invariant. Estimating Equation (2) by fixed effects would hence solve the identification problem, especially since there is no direct marketing to patients in Denmark that may vary over time. The grouping of the products is, however, time–invariant which makes it impossible to separately identify the fixed effects and the parameters related to the within groups market shares $s_{j|gt}$.

5 Estimation results

This section first discusses the estimation results for the price changes, it continues with the demand estimation findings and concludes with a discussion of the estimated own–price elasticities.

5.1 Prices

Table 5 displays aggregated results for our drug–specific Pooled Mean Group Estimates (PMGE) regressions of list prices on a constant term and a dummy variable for the respective block period as in Equation (1). We supplement these estimates with results from standard fixed effects estimation. PMGE and fixed effects regression results do not differ much. Our main interest is, however, in the drug–specific results which we make available for download from www.ulrichkaiser.com/papers/pharma.html, since we want to link these drug–specific price effect to the price elasticity of demand to back out demand changes due to price changes caused by the new reimbursement rules. The results shown in Table 5 are hence merely meant to describe overall patterns in the data.

The PMGE results displayed in Table 5 lump together very heterogenous effects of regulatory change on drug prices. Some products in fact encountered price increases across time as can be seen from the drug–specific estimates on our companion website.

The table shows that prices decreased on average in all time periods under consideration compared to the base period. The average absolute price change is, referring to PMGE results, -0.12 DKK per pill for the announcement period and -0.324 DKK for the implementation period.

The *absolute* changes in list prices are substantially higher for unbranded products than for branded products. Since list prices for branded products are much higher than for unbranded products, this implies that *relative* prices decreased more for unbranded products than for branded products.

5.2 Demand

Coefficients estimates

Estimation results for Equation (2) are shown in Table 6. The coefficient on price, specified as patients' co–payment, is negative and statistically highly significant when estimated with GMM. It does not have a direct economic interpretation and needs to be converted into price elasticities. Our estimated own–price elasticities is -0.3 and does not differ much from results found in other studies. Table 6 also shows that there are little differences between the price elasticities of demand of branded and unbranded drugs.

The within–group correlation parameter σ is statistically significant and positive. The point estimate for σ is 0.44 and statistically significantly smaller than 1 which means that patients' preferences are highly, but not perfectly correlated on the ATC/strength level.

6 Policy implications

This section combines the policy effects on prices and the demand estimation results to calculate the gains and losses from regulatory reform accruing to (i) the public health insurance, (ii) patients and (iii) producers. This define our last scenario, where both, demand and prices, react to the reform. Our estimates for the total effect of regulatory change on the three players operating on the market are presented in Table 7. As before, we summarize the results for different segments of products, classified according to its distribution of prices in the base period. Comparison is made from base period to implementation period.

A crucial issue worth mentioning is that those products for which we are able to compute health care reform effects are those which "survived". If products that were withdrawn from the market are those that were particularly adversely affected by the reform, then our estimates for patient and insurance savings as well as producer

revenue constitute a lower limit.

Consumers

Table 7 shows that consumers benefit from the new reimbursement system. Their per pill expenditures decreased by a median value of 22.5 percent over the entire time span. Savings were largest for buyers of cheapest products (-31.5%), while patients expenditures for the most expensive products decline only by 11%. Total changes in patients expenditures amount to a biweekly decrease of 2%.

List, reference and co-payment prices decline for all segments of products. Surprisingly the demand for cheapest products decline on average by -6.5% while the change for demand for the most expensive products is positive (50.7%). A possible explanation could be that since prices for all products decline, consumers substitute cheap medicines with more expensive ones, in contrary to the aims of the reform.

Insurers

The Danish public insurance also benefitted from the change in the health care system. Insurance payments per pill decreased by 24.2 percent on average. The highest saving where obtained from cheapest products, on average 31.5 percent per period. The lowest savings, on the other hand, came from the most expensive products, 11%. Total government savings amount to a biweekly decrease of 4%.

Producers

That the Danish health care reform has not been a zero sum game is clearly demonstrated by the losses in producer revenue. On average, revenue decreased by almost 24 percent after the reform was implemented. Losses were massive for the third group, the 50% to 75% more expensive products, where it reached 44%. Producers benefitted only in the most expensive group, where revenues were on average positive. Total producers revenue decreased -3.62% biweekly.

7 Conclusions

Denmark changed the way reference prices — a major determinant for patient reimbursement — for prescription drugs were calculated in April 1, 2005. Before the reform, reference prices were calculated based on average European prices. Reference prices have been calculated as the national minimum price within a group of substitutes since.

This paper investigates the joint effects of the health care reform on prices and demand. Since the April 2005 reform was discussed by policy makers and lobby groups long before its actual implementation, we consider three different block periods that may have had effects on prices and demand, namely a "base period", an "announcement period" and an "implementation period".

We first estimate the effects of the different periods of health care reform on prices, then estimate a model of demand for differentiated products and finally link the estimated own–price elasticities to our estimated price changes.

We show that from the base period to the announcement period co-payment prices decreased around 0.12 DKK on average and from the base period to the implementation period decreased around 0.32 DKK on average. Price reductions were more massive for unbranded products that for branded products.

We map the estimated price changes to our predicted quantity changes to calculate the relative changes in patients expenditures, insurance expenditures and producer revenue. We show that patients benefited from the health care reform. Their expenditures for co–payments decreased by 22.5 percent on average for all after the reform was implemented. Patients save most when buying the cheapest products. Total patient expenditures decreased around 2 percent biweekly.

The Danish health insurance system, which is paid through income taxes and insures all Danish residents, was positively affected as well. Reimbursements to patients decreased by 24.2 percent on average. Again, the cheapest products showed the highest savings for the government. Total expenditures decreased by 4 percent every second week.

Drug producers lost a quite substantial fraction of their revenue due to the reform. The average reduction is 12.5 percent with the largest reduction of 22.6 percent being allocated in the implementation period. Producers of unbranded drugs were much more adversely affected than producers of branded drugs. The reductions are 24 percent on average. Only in the segment of the most expensive products firms could show an increase in revenues of 5 percent on average. Total producers revenue decreased 3.6 percent biweekly.

While this paper quantifies the benefits and losses for the three main players in the health care system for products that existed in the base period and at least one of the other periods, we cannot say anything about the effects of the health care reform on the prices (and quantities) of drugs that entered after the base period. Moreover, we have to remain silent with respect to the effects of the reform on entry and exit. We leave the discussion of such dynamic effects of the reform for future research.

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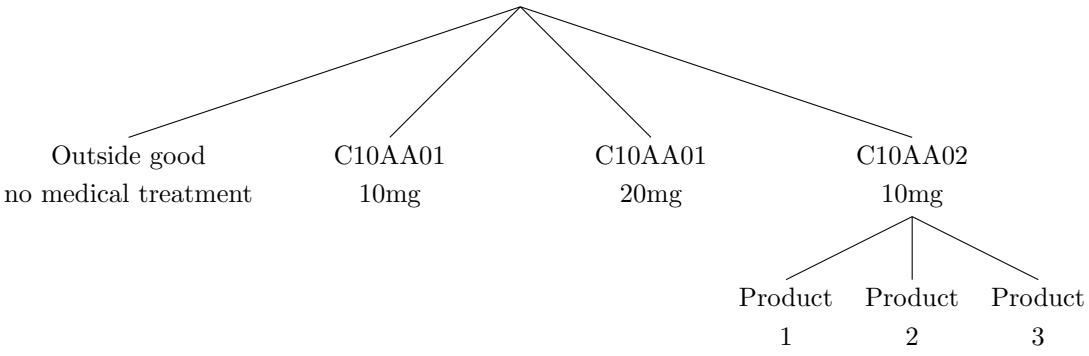

B Tables

Table 2: Summary of events related to changes in the Danish reimbursement system

LIF Agreement	20 Jan. 2003	Since 2001 LIF members and the Danish Ministry of Health have an agreement on price ceiling running until 2005. Not all active companies follow the agreement.
Adjustment	28 Apr. 2003	The Danish Medicine Agency starts updating pharmaceutical prices every 14 days. Before, reimbursement prices were set every 6 months
Base - Working group	15 Sep. 2003	The Danish Ministry of Health announces to assemble a working group that is asked to submit proposals regarding reimbursement rules with the aim to increase competition. The Association of Danish Pharmacies launches the idea that reimbursements should be based on the cheapest domestic product within substitute groups. The idea earns widespread support among leading politicians
Announcement	21 Jun. 2004	The law regarding the new reimbursement system is passed by the Danish parliament
Implementation	01 Apr. 2005	The new law is implemented
New LIF agreement	09 Oct. 2006	The LIF and the government agree upon on a price ceiling corresponding to the price on 30 Aug. 2006

C Figures

Table 3: Descriptive Statistics

	Mean	Median	Std. Dev.	Min.	Max.		Mean	Median	Std. Dev.	Min.	Max.
Base period											
Price	7.61	6.07	5.79	0.22	23.68	No. conglomerates	15.25	15	0.52	14	16
Transaction price	2.36	1.52	2.59	0	14.88	No. products entering	2.14	1	2.59	0	11
Reference price	6.60	4.45	6.01	0	23.96	No. products exiting	3.19	2	3.06	0	11
Sales (*1'000)	2'852.89	2'811.70	447.14	1'652.86	3'716.11	HHI	0.16	0.15	0.03	0.12	0.24
No. of products	143.02	145	5.90	126	151	C3	0.62	0.61	0.08	0.50	0.79
No. of producers	19.25	19	0.52	18	20	Share branded products	0.28	0.28	0.06	0.20	0.38
Discussion period											
Price	7.28	5.32	6.11	0.25	23.03	No. conglomerates	16.33	16	0.79	14	17
Transaction price	2.23	1.10	2.99	0	18.05	No. products entering	6	5	4.15	0	17
Reference price	6.25	4.10	6.12	0	23.31	No. products exiting	4.90	4	2.64	2	11
Sales (*1'000)	3'271.61	3'143.22	406.08	2'753.73	4'127.64	HHI	0.20	0.19	0.04	0.15	0.30
No. of products	150.46	152	9.45	126	162	C3	0.67	0.67	0.06	0.57	0.78
No. of producers	23.85	25	2.07	18	25	Share branded products	0.18	0.18	0.02	0.14	0.24
Implementation period											
Price	6.15	3.50	5.80	0.10	22.80	No. conglomerates	16.79	17	0.88	15	18
Transaction price	2.35	0.99	3.64	0	18.05	No. products entering	5.13	5	2.41	0	10
Reference price	4.71	1.96	5.27	0	22.36	No. products exiting	5.79	6	2.64	0	11
Sales (*1'000)	3'447.88	3'522.86	743.04	1'953.86	4'989.90	HHI	0.28	0.28	0.10	0.12	0.52
No. of products	147.13	155	15.85	114	165	C3	0.72	0.73	0.09	0.50	0.84
No. of producers	25.08	26	1.63	22	27	Share branded products	0.15	0.15	0.04	0.09	0.27

All prices in 2005 DKK per pill. Sales are given in no. of pills sold

Sales are given in no. of pills sold in 1′000

Table 4: Reform effect on prices

Product in x% in base period		Scenario 1 $\Delta p^l = 0$ $\Delta q = 0$						Scenario 2 $\Delta q = 0$					
		1%	25%	50%	75%	99%	Mean	1%	25%	50%	75%	99%	Mean
overall	p^l	.	.	.	.	.	.	-89.85	-49.87	-16.82	-2.89	103.46	-22.14
	p^r	-54.62	-5.92	-0.02	0.40	21.13	2.49	-81.22	-53.68	-23.69	-6.39	58.63	-26.87
	p^c	-41.11	-1.58	0.06	9.23	516.53	19.53	-95.93	-54.81	-8.32	6.81	669.72	11.75
0% - 25%	p^l	.	.	.	.	.	.	-54.73	-48.51	-26.21	-18.3	155.22	-13.16
	p^r	-17.34	-3.39	0.27	3.66	11.35	-0.63	-58.56	-49.79	-26.94	-14.24	83.58	-25.23
	p^c	-28.96	-12.35	-1.07	11.64	173.84	12.73	-59.79	-29.93	-16.36	17.56	844.91	67.8
25% - 50%	p^l	.	.	.	.	.	.	-61.86	-53.96	-38.08	-14.23	29.77	-33.62
	p^r	-36.54	-7.58	0	6.96	21.14	-2.96	-60.01	-50.08	-35.84	-20.14	23.83	-31.56
	p^c	-41.11	-7	0	16.28	90.59	12.45	-79.86	-69.5	-55.07	29.96	50.67	-29.23
50% - 75%	p^l	.	.	.	.	.	.	-90.14	-63.61	-52.02	-36.43	-13.29	-50.65
	p^r	-54.09	-14.59	-5.47	-0.13	15.81	-10.43	-64.38	-53.52	-31.89	-21.33	-0.88	-35.73
	p^c	-28.91	0.09	9.95	38.55	116.84	18.92	-97.01	-78.56	-58.62	-24.91	42.08	-49.76
75% - 100%	p^l	.	.	.	.		.	-37.6	-16.82	-13.01	-11.93	-10.44	-17.14
	p^r	-62.65	-32.25	-19.8	-2.45	884.9	33.67	-81.27	-61.83	-52.12	-24.14	-20.08	-48.29
	p^c	-78.23	1.81	5.19	42.99	535.82	87.43	-26.79	-12.18	5.94	326.12	669.71	171.26
Total change in government expenditures:							-2.18						-7.87
Total change in patients expenditures:							6.09						-10.07
Total change in producers revenue:							.						-9.7

Change of prices in percentage.

Scenario 1: List prices and demand are constant, change in reference prices.

Scenario 2: Demand is constant. Changes in list prices and reference prices. Changes in prices from "base" period to "Implementation" period.

Table 5: PMGE and fixed effects estimation results for absolute change in list prices per pill

	All Products		Branded Products		Unbranded Products	
	Coeff.	Std. err.	Coeff.	Std. err.	Coeff.	Std. err.
Mean Group Estimates						
Dummy for period 4	-0.121	0.032	-0.002	0.007	-0.339	0.064
Dummy for period 5	-0.324	0.051	-0.052	0.028	-0.622	0.074
Constant	1.639	0.105	2.548	0.059	1.199	0.117
Fixed Effects Estimates						
Dummy for period 4	-0.197	0.011	-0.004	0.004	-0.337	0.017
Dummy for period 5	-0.383	0.010	-0.045	0.004	-0.637	0.015
Constant	1.712	0.008	2.551	0.002	1.147	0.012
Observations		6'659		2'719		3'940
Products		92		35		57

Table 5 displays pooled mean group and fixed effects estimation results for a regression of the discounted list price on a constant term and a dummy variable for each of the considered time periods. The estimated coefficient is to be interpreted as the absolute change in list prices in the respective period compared to the base period. The coefficient estimates for the constant terms are the average list prices in the base period. The PMGE results are the means of drug–specific estimates.

Table 6: Results for OLS and GMM demand estimations

	OLS		GMM	
	Coeff.	Std. err.	Coeff.	Std. err.
α	0.11	0.01	-0.193	0.067
σ	0.875	0.007	0.448	0.051
Constant	-5.72	0.951	-7.607	0.285
Own price effects		all	branded	non-branded
Mean		-0.329	-0.305	-0.339

Estimations involve products observed in the base period. Standard errors are robust to serial correlation and heteroskedasticity. Package size dummies, period dummies and product name dummies are included

Table 7: Percentage effect of regulatory change

Product in x% in base period		1%	25%	50%	75%	99%	Mean
overall	q Demand	-19.48	-6.26	3.50	29.90	113.70	15.21
	p^l List price	-75.58	-57.43	-30.24	-11.38	58.19	-30.95
	p^r Reference price	-75.36	-58.50	-31.53	-10.99	62.63	-31.21
	p^c Co-payment price	-75.71	-54.77	-27.46	-10.09	53.17	-29.44
	Firm revenues	-67.97	-50.32	-30.89	-0.24	48.87	-23.98
	Government expenditures	-67.64	-52.85	-31.40	-0.27	50.35	-24.20
	Patient expenditures	-68.63	-48.30	-32.64	-0.15	48.72	-22.54
0% - 25%	q Demand	-19.48	-9.59	-6.76	-2.22	2.19	-6.50
	p^l List price	-67.85	-54.29	-20.31	3.08	16.02	-23.66
	p^r Reference price	-69.91	-58.03	-43.11	-11.21	14.53	-34.97
	p^c Co-payment price	-53.81	-33.35	-20.35	3.60	18.80	-17.80
	Firm revenues	-64.87	-58.34	-25.13	-0.83	18.56	-26.58
	Government expenditures	-64.57	-56.34	-40.09	-16.60	14.09	-34.37
	Patient expenditures	-65.28	-52.91	-36.57	-14.72	16.90	-31.53
25% - 50%	q Demand	-16.88	-7.61	-1.75	7.97	37.37	2.08
	p^l List price	-73.21	-58.54	-17.23	2.63	58.19	-21.34
	p^r Reference price	-75.36	-59.36	-15.86	-4.36	17.05	-27.97
	p^c Co-payment price	-73.76	-64.27	-18.98	6.46	53.17	-22.20
	Firm revenues	-67.97	-53.52	-26.02	1.07	31.48	-24.87
	Government expenditures	-55.84	-46.06	-19.63	9.14	30.13	-17.94
	Patient expenditures	-58.73	-44.33	-22.59	9.01	28.77	-17.79
50% - 75%	q Demand	-13.47	6.37	17.25	32.90	113.70	24.02
	p^l List price	-75.58	-62.54	-53.68	-43.29	-5.63	-51.44
	p^r Reference price	-72.69	-64.06	-29.01	-6.12	62.63	-28.35
	p^c Co-payment price	-75.71	-64.24	-55.73	-43.38	-17.58	-51.66
	Firm revenues	-56.62	-50.86	-47.83	-39.68	-14.03	-44.64
	Government expenditures	-67.24	-54.76	-33.16	1.90	35.17	-25.90
	Patient expenditures	-57.33	-51.62	-35.11	2.39	27.31	-25.63
75% - 100%	q Demand	4.12	26.91	49.65	79.59	100.22	50.70
	p^l List price	-70.25	-41.94	-17.10	-14.16	-10.68	-27.80
	p^r Reference price	-72.93	-49.80	-25.24	-16.76	-14.29	-32.66
	p^c Co-payment	-69.22	-43.46	-17.19	-14.40	-10.73	-28.04
	Firm revenues	-47.96	-22.68	13.35	35.34	48.87	5.20
	Government expenditures	-67.64	-53.48	-21.96	40.60	50.35	-14.22
	Patient expenditures	-68.63	-32.82	-21.32	34.77	48.72	-11.02
Total change in government expenditures:							-4.08 %
Total change in patient expenditures:							-1.99 %
Total change in producer revenue:							-3.62 %
Total demand change:							0.60 %

Changes in percentage from base to implementation period.

Table 8: Anatomical Therapeutic Chemical Classification for C10

2-Level	3-Level	4-Level	5 - Level	
C10 Lipid Modifying Agents	C10A	C10AA HMG CoA reductase inhibitors (Statins)	C10AA01	**simvastatin**
			C10AA02	**lovastatin**
			C10AA03	**pravastatin**
			C10AA04	**fluvastatin**
			C10AA05	**atorvastatin**
			C10AA06	cerivastatin
			C10AA07	**rosuvastatin**
			C10AA08	pitavastatin
		C10AB Fibrates	C10AB01	clofibrate
			C10AB02	bezafibrate
			C10AB03	aluminium clofibrate
			C10AB04	**gemfibrozil**
			C10AB05	fenofibrate
			C10AB06	simfibrate
			C10AB07	ronifibrate
			C10AB08	ciprofibrate
			C10AB09	etofibrate
			C10AB10	clofibride
		C10AC Bile acid sequestrants	C10AC01	**colestyramine**
			C10AC02	**colestipol**
			C10AC03	colextran
			C10AC04	**colesevelam**
		C10AD Nicotinic acid and derivatives	C10AD01	niceritrol
			C10AD02	nicotinic acid
			C10AD03	nicofuranose
			C10AD04	aluminium nicotinate
			C10AD05	nicotinyl alcohol (pyridylcarbinol)
			C10AD06	**acipimox**
			C10AD52	nicotinic acid, combinations
		C10AX Other lipid modifying agents	C10AX01	dextrothyroxine
			C10AX02	probucol
			C10AX03	tiadenol
			C10AX05	meglutol
			C10AX06	omega-3-triglycerides incl. other esters and acids
			C10AX07	magnesium pyridoxal 5-phosphate glutamate
			C10AX08	policosanol
			C10AX09	**ezetimibe**
			C10AX10	alipogene tiparvovec
	C10B	C10BA combinations	C10BA01	lovastatin and nicotinic acid
			C10BA02	**simvastatin and ezetimibe**
		C10BX combinations	C10BX01	simvastatin and acetylsalicylic acid
			C10BX02	pravastatin and acetylsalicylic acid
			C10BX03	atorvastatin and amlodipine

Source: WHO Collaborating Centre for Drug Statistics Methodology.
Detailed ATC codes for complete lipid modifying agents group (C10).
Only boldfaced chemical substances are marketed in Denmark.

Table 9: LMAs market shares

	2003	2004	2005	2006	2007	2008
Statins	90.91	92.50	91.92	90.53	88.89	87.04
Fibrates	6.06	4.00	3.54	4.74	3.17	3.09
Bile acid sequestrants	1.82	1.50	1.52	1.58	1.59	2.47
Nicotinic acid and derivatives	1.21	1.00	1.52	1.58	0.53	0.62
Other lipid modifying agents	.	1.00	1.52	1.58	2.65	3.09
Combinations	.	.	.	.	3.17	3.70
Total No. of products	165	200	198	190	189	162

Shares in percentage of lipid modifying agents by type and year.

Table 10: Quartile transition from base to implementation period

		Implementation			
	Base period	0% - 25%	25% - 50%	50% - 75%	75% - 100%
p^l	0% - 25%	10	3	3	0
	25% - 50%	3	4	4	1
	50% - 75%	3	4	5	1
	75% - 100%	0	1	1	9
p^r	0% - 25%	8	7	1	0
	25% - 50%	6	2	3	1
	50% - 75%	2	2	6	3
	75% - 100%	0	1	3	7
p^c	0% - 25%	14	2	0	0
	25% - 50%	2	8	2	0
	50% - 75%	0	2	10	1
	75% - 100%	0	0	1	10

Transition matrix of prices from base period to implementation period.